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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,793	09/19/2000	Volker Zimmer	RDID0043US	1444

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EXAMINER

ALEXANDER, LYLE

ART UNIT PAPER NUMBER

1743

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/554,793

Applicant(s)

ZIMMER, VOLKER

Examiner

Lyle A. Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7 and 9-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7 and 9-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5,7 and 9-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The new claims language "such that the detection element is downstream of the cover" is vague and indefinite as to the actual position of the cover. The language does not exclude the cover from also being upstream. If the cover can be both upstream and down stream, it appears the structure could be read on any cover. It seems that Applicant might be intended a specific structure that is only downstream of the detection element.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-5,7 and 9-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,592,815. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a device and method of use comprising a first layer, a detection layer and a cover having a notch to apply the sample. The cover layer is both upstream and downstream from the detection zone and has been properly read on it.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-5,9-14,16-18,21-22,24-27,30-31,33-34 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Douglas et al. (USP 5,843,691) or Zimmer (USP 5,814,522).

See the appropriate paragraph of the 6/23/04 Office action.

With respect to the new claim language directed to "such that the detection element is downstream of the cover", the Office maintains Douglas et al. teach a cover that extends both upstream and downstream from the detection element .

Zimmer teach in fig.(3) a cover(8) this is downstream from the reagent(6). Capillary gap(11) has been read on the claimed notch. Alternatively, Fig. (4) teaches cover(8) downstream from reagent(6/7) and gap(11) that has been read on the claimed notch.

***Claim Rejections - 35 USC § 103***

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2,3,19,20,28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas or Zimmer (USP 5,814,522) either in view of Columbus, Hodges or Lija.

See the appropriate paragraph of the 6/23/04 Office action.

Zimmer is being applied in the identical manner as Douglas.

Claims 7,15,23 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas or Zimmer (USP 5,814,522) either in view of Hodges and together further in view of Heller.

See the appropriate paragraph of the 6/23/04 Office action.

Zimmer is being applied in the identical manner as Douglas.

### ***Response to Arguments***

Applicant's arguments filed 4/14/05 have been fully considered but they are not persuasive.

Applicants' state Douglas et al. fail to teach a first and second edge. The Office maintains Douglas et al. do teach first and second edged on the cover as the taught cover is a 3-dimensional object and must have a first and second edge.

Applicants state the instant claims are directed to a sample hole(30) the is spaced from an end of the bottom layer(26). These remarks are not commensurate in scope with the pending claims that are not limited to these structures.

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Applicants state Douglas fails to teach "a carrier.... to the at least one notch is exposed". The Office maintains Douglas and Zimmer both meet these limitations.

Applicants state the art fails to teach the limitations of claims 16, 17 and 26. The Office maintains these limitations are sufficiently broad to have been properly read on Douglas and Zimmer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

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